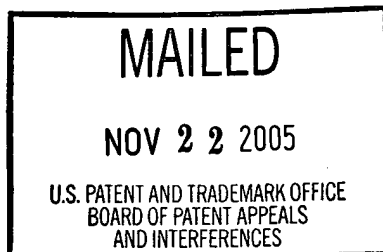


The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PHILLIP D. COOK and ANDREW M. KAWASAKI



Appeal No. 2005-2202
Application No. 09/996,263

ON BRIEF

Before ELLIS, ADAMS and GRIMES, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the examiner's final rejection of claims 8-13, the only claims remaining.

Claim 8 is representative of the subject matter on appeal and reads as follows:

8. A mixed sequence oligonucleotide or oligonucleotide analog including more than one 2'-modified 2'-deoxyfuranosyl moiety wherein said modification comprises substitution by halo, azido, amino, alkoxy, thioalkoxy, alkylamino, or alkyl, and wherein one of said 2'-modified 2'-deoxyfuranosyl moieties is different from another of said 2'-modified 2'-deoxyfuranosyl moieties.

The reference relied upon by the examiner is:

Draper et al. (Draper)	5,612,215	March 18, 1997
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Claims 8-13 stand rejected under 35 U.S.C. § 102(b) as anticipated by Draper.

We have carefully considered the respective positions of both the appellants and the examiner and find ourselves in substantial agreement with that of the appellants.

Accordingly, we reverse.

Background and Discussion

As indicated by the claim above, the present invention is directed to compositions of sugar-modified oligonucleotides. These compositions are hybridizable with a preselected nucleotide sequence of nucleic acid and are resistant to nuclease degradation. See Specification, p. 5, lines 12-20. For therapeutic purposes, it is desirable that the preselected sequence is involved in the production of a protein whose synthesis is ultimately to be modulated or inhibited in its entirety. See Specification, the Abstract.

The examiner entered a final rejection of claims 8-13 under 35 U.S.C. § 102(b) as anticipated by Draper. According to the examiner, "[t]he oligos of Draper[] comprise phosphorothioated nucleotide[] sequences containing both 2'-O-methyl moieties, and 2'-C-allyl modifications (see claim 20), thus meeting all the limitations of all pending claims." Answer, p. 4.

In reply, the appellants argue that the examiner's final rejection of claims 8-13 in view of claim 20 of Draper should be reversed. To overcome Draper, the appellants

claim priority to Cook.¹ The filing date of the Cook patent, March 5, 1992, precedes the earliest effective filing date of the Draper patent, Feb. 17, 1995.

The examiner argues that the Cook specification, as originally filed, does not provide an adequate written description of the claimed invention and, therefore, the appellants are not entitled to the benefit of the Cook filing date under 35 U.S.C. § 120. Answer, pp. 5 and 7. The examiner acknowledges that the Cook specification describes a combination of 2'-methylthio and 2'-O-methyl modifications which falls within the instant scope of the claims; however, he contends that "said combination is not considered to provide adequate support for any oligo containing two or more different modifications chosen from the broad list now claimed." Id., p. 5. According to the examiner, adequate support is lacking because the context of the disclosure contains no mention of any advantages or the desirability of said combination, but only discloses that they were made. Id. at 6.

In response, the applicants have submitted a Declaration of Dr. Sidney M. Hecht pursuant to 37 C.F.R. § 1.132. Dr. Hecht contends that the Cook specification's disclosure of oligonucleotides having a combination of 2'-methylthio and 2'-O-methyl modifications must be read in conjunction with the disclosure found in col. 7, lines 43-54 which reads:

Oligonucleotide analogs particularly suited for the practice of one or more embodiments of the present invention comprise 2'-sugar modified oligonucleotides wherein one or more of the 2'-deoxy ribofuranosyl moieties of the nucleoside unit is modified with a hydrogen or hydroxyl,

¹ Cook et al. (Cook), U.S. Patent No. 5,670,633, issued Sep. 23, 1997.

halo, azido, amino, alkoxy, thioalkoxy, alkylamino or alkyl group. For example, the substitutions which may occur include H, OH, F, CN, CF₃, OCF₃, OCN, O-alkyl, S-alkyl, SOMe, SO₂Me, ONO₂, NO₂, N₃, NH₂, NH-alkyl, OCH=CH₂, OCCH where alkyl is a straight or branched chain of C₁ to C₁₂ with unsaturation within the carbon chain such as allyloxy.

Dr. Hecht characterizes this list of possible substitutions as a list that should not to be read in the alternative. Dr. Hecht's Declaration, ¶ 13. On the other hand, the examiner argues that this disclosure is a list presented in the alternative which requires that more than one nucleotide on a particular oligo may be modified and all modifications are to be of the same type. Answer, pp. 8-9.

We find the appellants' argument persuasive only after considering the Cook specification as a whole.

The purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field as far as described in the patent specification." Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000). To that end, to satisfy the written description requirement, the inventor "must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [first emphasis added]. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). "One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations . . ." [emphases in original]. Lockwood v. American Airlines, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

We point out that it is not necessary for the specification to describe the claimed invention ipsissimis verbis; all that is required is that it reasonably convey to those skilled in the art that, as of the filing date sought, the inventor was in possession of the claimed invention. Union Oil of California v. Atlantic Richfield Co., 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000); Vas-Cath Inc. v. Mahurkar, 935 F.2d at 1563-64, 19 USPQ2d at 1119; In re Gosteli, 872 F.2d 1008,1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989); In re Edwards, 568 F.2d 1349, 1351-52,196 USPQ 465, 467 (CCPA 1978).

In the present case, we find the disclosure in col. 7, lines 43-54 of the Cook specification, when considered in isolation, to be vague and susceptible to either the examiner's or the appellants' interpretations. As such, it is not dispositive except when read in conjunction with the disclosure of oligonucleotides having a combination of 2'-methylthio and 2'-O-methyl modifications, as set forth in Example 13, and other portions of the Cook specification. Therefore, the issue of whether the appellants' priority claim to the Cook patent should be granted requires an examination of the specification in its entirety to determine if it satisfies the written description requirement of § 112, first paragraph.

We agree with the appellants, after review of the Cook specification, that the parent application reasonably conveys to those skilled in the art that the inventor was in possession of an oligonucleotide containing two or more different modifications chosen from the list found in claims 8-13. Specifically, the Cook patent discusses prior art in

which oligonucleotides having 2'-O-methyl modifications in each nucleotide were made and that 2'-methoxy oligonucleotides facilitate greater hybridization stability, primarily due to the absence of steric effects from a hydroxyl group. Cook, col. 3, line 65 to col. 4, line 10. The specification further discloses the possibility of incorporating 2'-deoxy-2' halo, azido, amino and methoxy nucleoside monomers into sequence specific oligonucleotides. Cook, col. 4, lines 11-19. A more detailed list of the possible substitutions in the present invention of 2'-sugar modified oligonucleotides is described in the aforementioned col. 7, lines 43-54. Cook describes that they made various RNA mimics in order to find oligonucleotides that exhibited both nuclease resistance and a greater binding affinity to RNA targets. Cook, col. 10, lines 1-23. Subsequently, Cook exemplified the generic disclosure by describing the manufacture of four oligonucleotides having 2'-deoxy-2'-fluoro moieties at various nucleotide positions. Cook, col. 28, lines 1-26. Finally, the same example describes the incorporation of 2'-deoxy-2'-methylthio substituents into oligonucleotides to assess their coupling efficiencies and that some oligonucleotides were made such that all the nucleotides contained either a 2'-deoxy-2'-methylthio substituent or a 2'-O-methyl substituent. Cook, col. 28, lines 27-52. Since Cook states that nucleotide modifications are the same as those recited in claims 8-13, we find that, in its entirety, the disclosure provides written descriptive support for the claimed oligonucleotides having more than one 2'-modified 2'-deoxyfuranosyl moiety wherein one moiety differs from another.


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Thus, in considering the teachings of the Cook patent as a whole, we find that it satisfies the written description requirement of § 112, first paragraph. The context of the disclosure describes that nuclease resistance and increased coupling efficiency is achievable through oligonucleotides having two or more different modifications chosen from the broad list now claimed. Therefore, our examination of the specification determines that the appellants are entitled to the benefit of the Cook filing date under 35 U.S.C. § 120. Because the appellants have this benefit, Draper is not available as prior art.

Accordingly, in view of the foregoing, the rejection is reversed.

REVERSED


JOAN ELLIS
Administrative Patent Judge


DONALD E. ADAMS
Administrative Patent Judge


ERIC GRIMES
Administrative Patent Judge

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